# Translating Evidence Reviews Into Methodological Guidance

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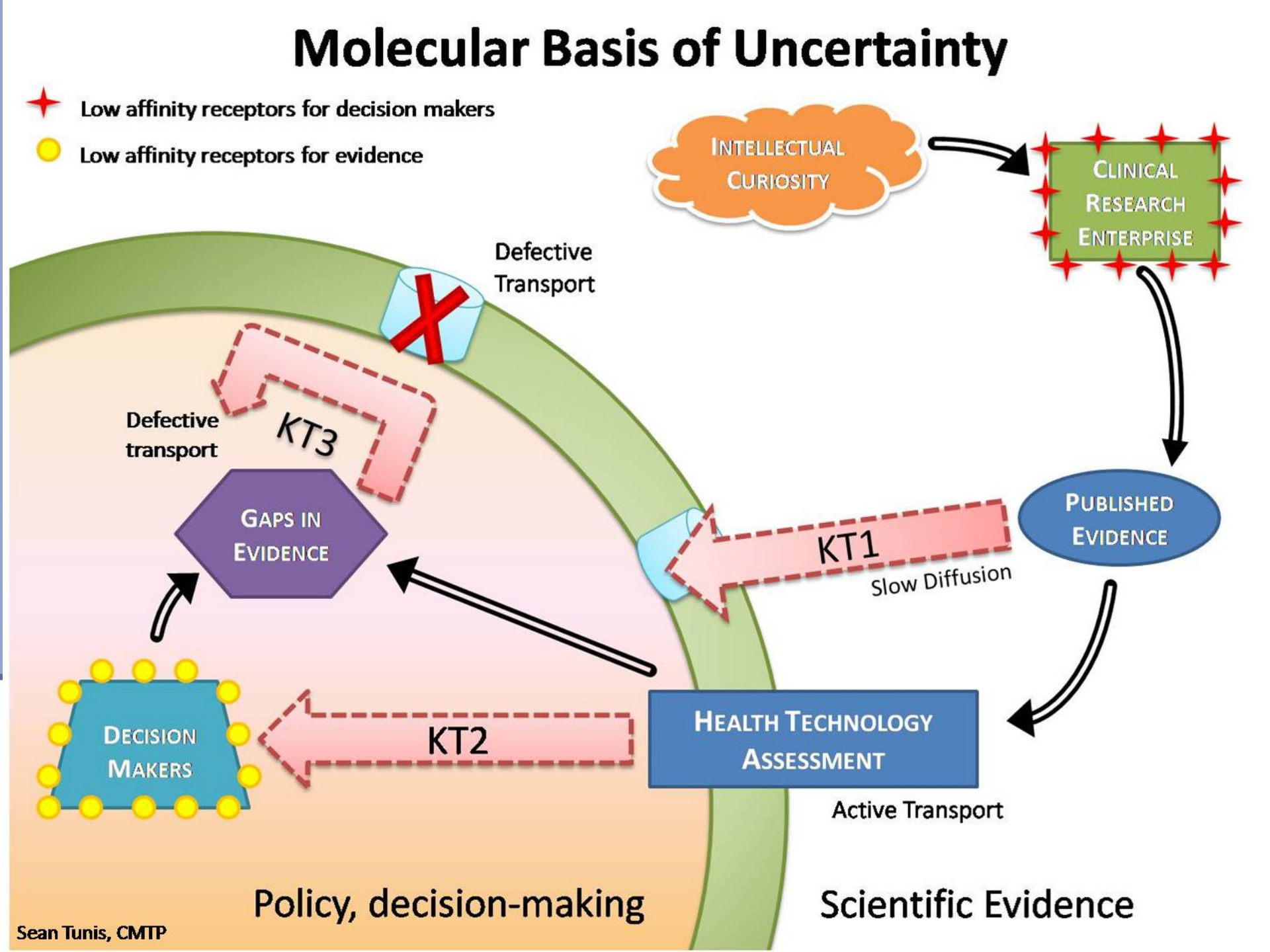
# IOM Committee's Definition of CER

The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians,, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels.

# Molecular Basis of Uncertainty



# SACGHS recommendation

- "Information on clinical utility is critical for managing patients, developing professional guidelines, and making coverage decisions."
- "HHS should create a public private entity of stakeholders to….establish evidentiary standards and levels of certainty required for different situations"

# Effectiveness Guidance Documents (v 1.0)

- Analogous to FDA-guidance
- Recommendations for study design reflecting evidence needs of patients, clinicians, payers
- Targeted to product developers, clinical researchers
- Objective is to provide “reasonable confidence of improved health outcomes”
- Initial topics:
  - GEP for breast cancer
  - Treatment of chronic wounds
  - Non-invasive cardiac imaging

# GEPBC Workgroup

- Patient/consumer
- Clinical oncologist
- ASCO
- Private payers
- CMS (local/national)
- Clinical researchers
- Biostatisticians
- FDA
- AHRQ
- CDC/EGAPP

# EGD Development Process

- Starts with JHU EPC report on GEP
- JHU / CMTP generate initial draft guidance
- Advisory group oral and written comments
- Revised draft circulated for public comment
- Revisions based on public comment
- Conference being planned to address key unresolved issues
- Balancing validity, relevance feasibility, and timeliness is not easy!

# Review Methods vs Guidance

- Teutsch (Table 4): "What was the relative importance of outcomes measured; which were pre-specified primary outcomes and which were secondary"
- CMTP EGD: "Valid outcomes or surrogates for breast cancer prognosis include distant recurrence at 5 or 10 years, disease free survival, disease specific mortality, and overall survival"

# Teutsch et al - Methods of the EGAPP Working Group (Jan 09)

- "Genetic tests tend to fit less well within the "gold-standard" processes" for reviews
- Lack of well designed clinical trials or observational studies of validity / utility
- Describes process and framework for linking evidence to EWG recommendations
- Criteria for assessing quality of individual studies and grading quality of evidence
- Not intended to provide direct study design recommendations to product developers

# EGAPP Recommendations on GEP for Breast Cancer (Jan 09)

- Based on JHU systematic review
- Applies EGAPP methods framework
- Insufficient evidence to make recommendation for or against use of GEP to improve outcomes
- “EWG found preliminary evidence of potential benefit of testing results to some women”
- “No firm guidance can be given to clinicians” until TAILORx and MINDACT trials completed
- Challenging standard, from developer viewpoint

# Finance Committee Report Oct 19, 2009

- "Within two years of enactment (with periodic updates) the methodology committee would determine a process to establish and maintain detailed methodological standards for comparative clinical effectiveness studies. The standards would provide criteria for study designs that balance generalizability, timeliness and other factors."

# Contact Info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# CMTP Purpose

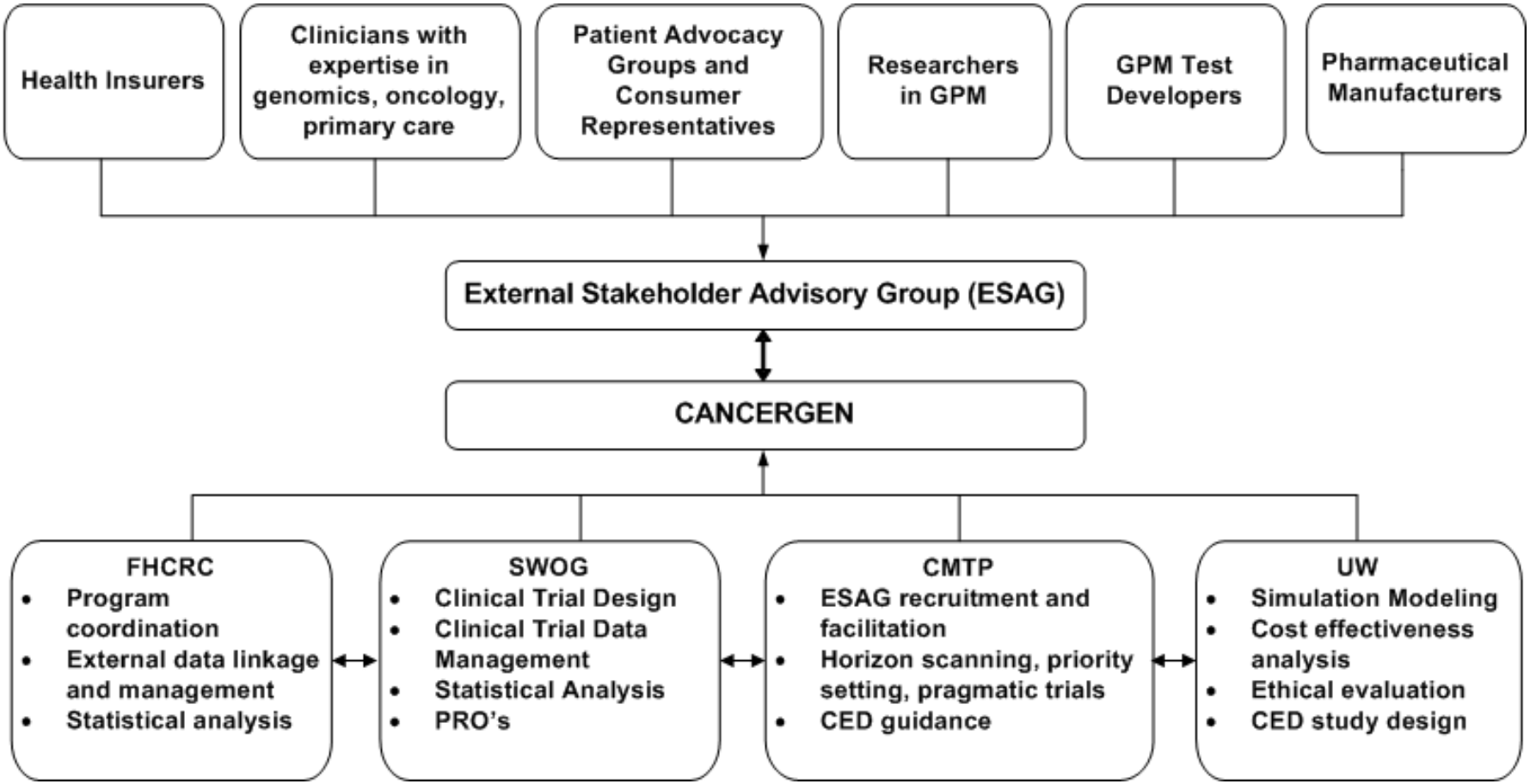
- Provide a neutral forum for collaborative projects to conduct clinical research that it is more informative to decision makers
  - patients, consumers, clinicians, payers and policymakers.
- We don't implement CER studies; we develop methods, policies, and collaborations to make them happen

# CMTP Basics

- Started Jan 2006 within HealthTech in SF
  - CHCF and Blue Shield California Foundation
- Incorporated as 501c3 in Jan 2008 (Maryland)
  - 5 member governing board; 14 on advisory board
- Funding
  - Founding members:  Blue Shield California, Kaiser, United, Aetna NPC, Pfizer, Amgen, JNJ
  - Additional funds from foundations, government, professional societies
- Staffing:  14 FTEs

CMTP
Center for Medical Technology Policy

# CANCERGEN Structure

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